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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,640

04/09/2004

Mark A. Holland

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EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

07/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,640	Applicant(s) HOLLAND ET AL.	
	Examiner NICOLE KINSEY WHITE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-10,23,24,49-52 and 57-66 is/are pending in the application.
- 4a) Of the above claim(s) 57-66 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,10,23,24 and 49-52 is/are rejected.
- 7) ☒ Claim(s) 2 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

New claims 57-66 are withdrawn as being directed to non-elected subject matter. Accordingly, claims 1, 2, 4, 5, 7-10, 23, 24, and 49-52 are under examination.

Claim Objections

Claim 10 is objected to because of the following informalities:

Claim 10 recites improper Markush language. The claim should recite “and combinations thereof” instead of “or combinations thereof”, and the claim is missing a period at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 23, 24, and 49-52 remain are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to, *inter alia*, an isolated bacteriophage which is lytic for *Methylobacterium* species, Human blood bacterium (HBB), or both. Applicants have

isolated and deposited bacteriophage that is lytic for *Methylobacterium* species and Human blood bacterium as ATTC# PTA-5075. However, applicants' claims encompass bacteriophage that are lytic for *Methylobacterium* species and Human blood bacterium and that are structurally and biologically different from ATTC# PTA-5075.

The written description rejection is made because the claims are interpreted as being drawn to a genus of bacteriophage which possesses the function of being lytic for *Methylobacterium* species or Human blood bacterium. The applicable standard for the written description requirement can be found in MPEP 2163; *University of California v. Eli Lilly*, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609; *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111; and *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CAFC 2004). To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the specification is the function of the bacteriophage being claimed. There is no disclosure of sufficient characteristics of the claimed genus to allow persons of ordinary skill in the art to recognize that applicants were in possess of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the

claimed genus. A definition by function alone is not sufficient because it is only an indication of what a thing does, rather than what it is. *EliLily*, 119 F.3 at 1568, 43 USPQ2d at 1406.

The court clearly states in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented what is claimed. As discussed above, the skilled artisan cannot envision the distinguishing, identifying characteristics of the encompassed genus of bacteriophage. Given that the specification has only described the function of the bacteriophage, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Response to Arguments

In the reply dated April 9, 2008, applicants argue that applicants were clearly in possession of the class of bacteriophage as evidenced by the specific bacteriophage described in the specification. Applicants also submitted a Declaration under 37 CFR §1.132 by Richard Carlton, M.D. Applicants’ arguments and Declaration have both been fully considered, but are not found persuasive.

As outlined above, applicants have not provided sufficient identifying characteristics of the genus of bacteriophage encompassed by the claims. Applicants

have only isolated (deposited) one phage (ATTC# PTA-5075) that is lytic for *Methylobacterium*.

Applicants' Declaration states that there is abundant evidence from a variety of authoritative sources that the phage isolated by Professor Holland represents something that is generalizable (repeatable). The Declaration further states that had Professor Holland wanted to find other phage strains, the collective experience of phage researchers would predict that Professor Holland would have found a smorgasbord of different phage strains.

The fact that applicants isolated a phage using a repeatable or generalizable process is not at issue nor is what Professor Holland would have found had he searched for additional strains of phage that were lytic for *Methylobacterium*. What is at issue is whether or not applicants have provided adequate written description of the claimed genus. As outlined above, describing or depositing only one specific phage is not sufficient to show that applicants were in possession of the genus of phages that are lytic for *Methylobacterium*.

On page 5 of the Declaration, applicants argue that:

[o]nce Professor Holland had obtained that virulent anti-PPFM phage strain, and had demonstrated that it worked well in decreasing the rate (and vigor) of germination of seeds, he had no scientific need to search and isolate even more such phage strains, in addition to the variety he had already obtained. His quest was not that of a phage epidemiologist, who would want to find out how many strains of phages (against the target bacterial species) are present, or what they look like morphologically, or what their genetics are.

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Applicants' statement supports the assertion that applicants were not in possession of the claimed genus because there was "no scientific need to search and isolate even more such phage strains" beyond the anti-PPFM strain ATTC# PTA-5075. Professor Holland was interested in finding one phage to suit his purposes (seed-curing). When he isolated that one phage, he looked no further. One phage is not sufficient to fully describe a genus of phages that all share the same function of lysing *Methylobacterium*. Describing many strains of phages against *Methylobacterium*, or describing what they look like morphologically, or describing their genetic makeup would provide additional support that applicants were in possession of the claimed genus, however, the specification does not describe such characteristics. Therefore, because there is no disclosure of sufficient characteristics of the claimed genus, one of ordinary skill in the art would not recognize that applicants were in possession of the claimed genus.

Allowable Subject Matter

Claims 7-9 are allowable.

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648

<div><i>Application Number</i></div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/821,640	HOLLAND ET AL.	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	